APR - 2 2003

K030323

510(k) Summary

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Submitted by

Mammendorfer Institut für Physik und Medizin GmbH
Oskar-von-Miller-Strasse 6
82291Mammendorf / Munich, Germany

510(k) Correspondent

Robert N. Clark, President and Senior Consultant
Medical Device Regulatory Advisors
13605 West 7th Ave., Golden, CO USA
Tel: 303-234-9412 / Fax: 303-234-9413

Date Prepared

January 24, 2003

Trade Name of Device

MRI-Caddy

Common Name of Device

Infusion Pump

Classification Name

Infusion Pump

510(k) Classification

880.5725 Class II

Device Description and Intended Use

The MRI-Caddy® is a cart with an integrated chassis, which is equipped with three Medex syringe pumps and a power supply. The MRI-Caddy's mechanical construction makes it possible to position the system with the MR-room. For this purpose the system was equipped with adequate screening following the principle of a Faraday cage. The function principle corresponds to that of the Medex syringe pumps already on the market.

Predicate Devices

Syringe Infusion Pump, Model 3001 Syringe Infusion Pump, and Medfusion Model 2001 Syringe Infusion Pump manufactured by Medex, Inc.

The basic design, material, chemical composition of the Medex pump series 2000 used in the MRI-Caddy are the same as for the current corresponding Medex Medfusion model pumps. They are identical in operation, function, features, and form as their predicate devices, and represent no technological differences.

Non-Clinical Testing

The requirements of the following standards have been used in part to establish substantial equivalence:

EN 60601-1 / IEC 601-1 "Medical Electrical Equipment – Part 1: General Requirements for Safety", including Amendment 1 (1991) & Amendment 1 (1995)

The company did not conduct, nor depend on, clinical studies in order to establish substantial equivalence.

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program.

The user must be qualified in MRI and infusion pump procedures, and must be familiar with all labeling and instructions for use associated with the device. The company believes many device health hazards are due to user error, or failure to follow instructions for use.

Mammendorfer Institut für Physik und Medizin GmbH believes that the MRI-Caddy is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mammendorfer Institut Für Physik und Medizin GmbH
C/O Mr. Robert N. Clark
Medical Device Regulatory Advisors
13605 West 7th Avenue
Golden, Colorado 80401

Re: K030323
Trade/Device Name: MRI-Caddy®
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: January 24, 2003
Received: January 30, 2003

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

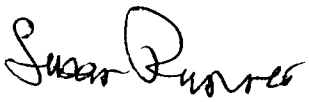
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K030323

Device Name: **MRI-Caddy®**

Indications for Use:

The intended medical application of MRI-Caddy with three 2000-Series syringe pumps is to produce controlled movement of the plunger of a syringe to inject a set amount of therapeutic fluid into a patient within a hospital setting at a set rate and at set times. The MRI-Caddy is designed for use in an MR-environment at a maximum magnetic field strength of 20mT.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucuzzella

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030323

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)